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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,636	06/13/2001	Mary Faris	G&C 129.12-US-U1	7272

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EXAMINER
YU, MISOOK

ART UNIT	PAPER NUMBER
1642	8

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/881,636	FARIS ET AL.	
	Examiner	Art Unit	
	Misook Yu	1642	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

098881636

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 20, 42, and linking claims (13, 17-19, 41), drawn to 55P4H4-related ***protein*** of SEQ ID NO:2, fragments and variants, classified in class 530 subclass 300.

II. Claims 13-19, 45, 46, linking claims 41, drawn to pharmaceutical composition comprising 55P4H4 ***DNA*** as main active agent, classified in class 514, subclass 44.

III. Claims 21-29, 31, 32, 43, and linking claims 41, drawn to ***antibody***, hybridoma, classified in class 530, subclass 387.1.

IV. Claims 30, and linking claim 21, drawn to non-human transgenic animal, classified in class 800, subclass 8.

V. Claim 33, 44, and linking claim 32, drawn to vector encoding product of group III, classified in class 536, subclass 23.1 and others.

VI. Linking claims 34-36, drawn to method for detecting products of group I above, classified in class 435, subclass 7.1.

VII. Claims 37-40, Linking claims 34-36, drawn to method for detecting products of group II above, classified in class 435, subclass 6.

VIII. Claim 47, and linking claim 41, drawn to ribozyme, classified in class 514, subclass 42.

IX. Claim 48, and linking claim 44, drawn to treatment method using product of group V, classified in class 514, subclass 44.

X. Claim 49, and linking claim 41, drawn to method for inhibiting cancer using product of group I, classified in class 512, subclass 2 and others.

XI. Claim 49, and linking claim 41, drawn to method for inhibiting cancer using product of group II, classified in class 512, subclass 44.

XII. Claim 49, and linking claim 41, drawn to method for inhibiting cancer using product of group III, classified in class 424, subclass 130.1.

XIII. Linking claim 50, drawn to method of generating immune response using group I, classified in class 514, subclass 2.

XIV. Linking claim 50, drawn to method of generating immune response using group II, classified in class 514, subclass 44.

XV. Claim 51, and linking claim 21, drawn to method of delivering cytotoxic agent, classified in class 424, subclass 178.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions groups I, IV, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions groups I and VIII have different molecular structures with different biological activities and group IV is transgenic animal.

Inventions I and VI, X, XIIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of group VI, X, or XIIII.

Inventions II and VII, XI, XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of group VII, XI, or XIV.

Inventions III and XII, XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of group XII or XV.

Inventions V and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product could be used to make antibodies.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. The search required for each of the above inventions is not coextensive with regard to the literature and the sequence searches. Further, a reference which would anticipate the invention of any one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons, restriction for examination purposes is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, group I and II above are generic.

Group I contains claims generic to a plurality of disclosed patentably distinct species. The different peptide fragments listed in claim 5 and different HLA classes listed in claim 6 are patentably distinct because the different peptide fragments are different in chemical structure and molecular formulas and are different epitopes that may or may not recognized by a specific HLA class listed in claim 6. If group I is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the two genuses, even though this requirement is traversed. Please provide a SEQ ID NO of the elected species.

Group II contains claims generic to a plurality of disclosed patentably distinct species. The different fragments of SEQ ID NO:2 listed in claim 15 and different HLA

classes listed in claim 16 are patentably distinct because the different DNA fragments encode different epitopes that may or may not be recognized by the different HLA classes listed in claim 16. If group II is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the two genuses, even though this requirement is traversed. Please provide a SEQ ID NO of the elected species.

Group III contains claims generic to a plurality of disclosed patentably distinct species. The different peptide fragments listed in claim 22 are patentably distinct because the different peptide fragments are different in chemical structure and molecular formulas and are different epitopes. If group I is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Please provide a SEQ ID NO of the elected species.

Claim 40 is generic to a plurality of disclosed patentably distinct species comprising different cancers in Table 1. If any of the groups that contain claim 4 is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu, Ph.D.
July 11, 2002

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800

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